UNITED STATES PATENT APPLICATION

OF

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FOR

MECHANICAL HEART VALVE

MECHANICAL HEART VALVE

Continuing Data

[0001] This application claims priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 60/413,847, filed September 27, 2002, and claims priority under 35 U.S.C. §120 to pending U.S. Patent Application No. 10/143,810, filed May 14, 2002 and to its parent application, U.S. Patent Application No. 09/323,402, filed June 1, 1999, now U.S. Patent No. 6,395,024 whose disclosures are expressly incorporated by reference herein, and which claim priority under 35 U.S.C. §119(e) to U.S. Provisional Application No. 60/088,184, filed June 5, 1998, and under 35 U.S.C. §120 to U.S. Application No. 09/035,981, filed March 6, 1998, now U.S. Patent No. 6,068,657, and to its parent application, U.S. Application No. 08/859,530, filed May 20, 1997, now abandoned.

BACKGROUND OF THE INVENTION

Field of Invention

[0002] The present invention relates to an improved trileaflet mechanical heart valve. More specifically, the present invention relates to a trileaflet mechanical heart valve with improved flow characteristics. Such a mechanical heart valve is useful for surgical implantation into a patient as a replacement for a damaged or diseased heart valve.

Background Considerations

[0003] There are numerous considerations in the design and manufacture of a mechanical prosthetic heart valve. An important consideration is the biocompatibility of the materials used in the prosthesis. The materials used must be compatible with the body and the blood. Furthermore, the materials must be inert with respect to natural coagulation processes of the blood, *i.e.,* they must not induce thrombosis (an aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction at the point of its formation) when contacted by the blood flow. A local thrombus can give rise to an

embolism (the sudden blocking of a blood carrying vessel) and can even under certain circumstances hinder proper valve operation. Numerous materials have been tested for such desirable biocompatibility. Several materials are commonly used for making commercially available prosthetic heart valves (materials such as stainless steel, chromium alloys, titanium and its alloys, and pyrolytic carbon).

[0004] Another consideration in the design and manufacture of a mechanical prosthetic heart valve is the valve's ability to provide optimum fluid flow performance. Mechanical prosthetic heart valves often create zones of turbulent flow, eddies, and zones of stagnation. All of these phenomena can also give rise to thrombosis and thrombo-embolisms. Biological valves (or bioprostheses) emulate the form and the flow pattern of the natural heart valve and thus have better fluid flow performance over conventional mechanical prostheses. Such bioprosthetic valves do not require long-term anti-coagulant medication to be taken by the patient after implantation at least in the aortic position. These two thrombus-generating factors (materials used and flow characteristics) are problematic in conventional mechanical heart valve prostheses. Thus, patients who currently receive a mechanical heart valve prosthesis require a continuous regime of anti-coagulant drugs which can result in bleeding problems. The use of anti-coagulant drugs therefore constitutes a major drawback of mechanical heart valve prostheses when compared with bioprostheses.

[0005] However, biological replacement valves suffer from problems too. As clinical experience has indicated, unlike mechanical valves, their life-span is often too short. Because of the progressive deterioration of bioprostheses, they often need to be replaced via costly additional major surgery.

[0006] Yet another consideration in the design and manufacture of a mechanical prosthetic heart valve concerns the head loss (pressure drop) associated with the valve. This head loss occurs during the systolic ejection or diastolic filling of a ventricle. In conventional designs, some head loss is inevitable since it is inherent to the reduction in the effective orifice area of the mechanical prosthetic heart valve as compared to natural valves. The reduction in effective orifice is caused by the sewing ring which is conventionally required for surgical installation of

the prosthetic valve, by the thickness of the valve housing, and by the hinges which enable the valve's flaps (leaflets) to move between an open and closed position. Another portion of the head loss is due to the geometric disposition of the valve's flaps with respect to the flow of blood. Yet another portion of the head loss is due to the wetted surface area of the valve housing.

[0007] As mentioned above with respect to the progressive deterioration of bioprostheses, durability is another consideration in the design and manufacture of a mechanical prosthetic heart valve. A mechanical prosthetic heart valve should demonstrate a mechanical lifetime equivalent to approximately 380 - 600 million cycles (*i.e.,* the equivalent of about 15 years). Obviously, the mechanical lifetime is related to the geometrical design of the valve as well as the mechanical characteristics of the materials used.

[0008] Of course, the valve's ability to minimize leakage is also important. Leakage generally comprises regurgitation (backward flow of blood through the valve during operation, and otherwise known as dynamic leakage) and static leakage (any flow through the valve in the fully closed position). In the conventional valves, the amount of regurgitation is at least 5% of the volume of blood flow during each cycle, and is often more. When a patient has two prosthetic valves on the same ventricle, regurgitation (dynamic leakage) thus comprises at least about 10% (leakage on the order of several hundred L per day). Thus, dynamic leakage clearly puts undesirable stress on the heart muscle. Static leakage, on the other hand, is typically caused by the imperfect mechanical sealing of the prosthetic valve when its flaps are closed. Because static leakage also causes the heart muscle to work harder, it must be taken into consideration in the design and manufacture of a mechanical prosthetic heart valve.

[0009] The closing mechanism of natural cardiac valves has not been taken into account in the design of conventional mechanical valve prostheses. When the flow rate across the valve becomes zero, the natural aortic valve is already more than 90% closed. In contrast, conventional mechanical valve prostheses at that same time remain almost fully open. From this almost fully open position, conventional mechanical valve leaflets abruptly close with the large amount of regurgitation. In an aortic position, this occurs at the very beginning of the diastole,

and in the mitral position, this occurs even more abruptly at the very beginning of the systole. In conventional mechanical leaflets, the mean closing velocity of some portions of the leaflets (at 70 beats per minute) is on the order of 1.2-1.5 m/sec, whereas the highest closing velocity in a natural valve is 0.60 m/sec. Rapid angular closing speeds create cavitation in mechanical prosthetic heart valves. This high closure speed increases the intensity of the impact of the leaflets upon closure and thus, generates sufficiently large acoustical vibrations to cause discomfort in the patient, damages the blood (embolisms), and generates micro-bubble formations in the blood which may be detected by a transcranial doppler (HITS - High Intensity Transcranial Signals).

[0010] Thus, conventional mechanical heart valves suffer from several disadvantages. First, conventional mechanical heart valves fail to provide optimal blood flow characteristics. Next, conventional mechanical heart valves allow blood to stagnate behind the valve leaflets, thus creating the possibility of blood clotting in those locations. Also, conventional mechanical heart valves may not provide optimum opening and closing times (*e.g.*, times which properly emulate a natural human valve). It has not been possible, in the past, to reproduce the flow characteristics of a natural valve when using a mechanical prosthesis. Thus, with the use of conventional mechanical heart valves, embolic incidents and subsequent mortality may be directly or indirectly linked to the valve prosthesis.

[0011] Accordingly, there is a need for an improved mechanical heart valve for implantation into a patient which provides improved flow characteristics, minimizes blood clotting behind the leaflets, and provides more natural opening and closing behavior.

SUMMARY OF THE INVENTION

[0012] Accordingly, the present invention is directed to an improved mechanical heart valve for surgical implantation into a patient which substantially eliminates one or more of the problems or disadvantages found in the prior art.

[0013] An object of the present invention is to provide for an improved mechanical heart valve for surgical implantation into a patient which provides improved flow characteristics.

[0014] Another object of the present invention is to provide for an improved mechanical heart valve for surgical implantation into a patient which minimizes the potential for blood clotting behind the leaflets.

[0015] Another object of the present invention is to provide for an improved mechanical heart valve for implantation into a patient which provides improved (*e.g.*, more natural) opening and closing behavior.

[0016] Another object of the present invention is to provide for an improved mechanical heart valve for implantation into a patient which provides reduced regurgitation and closure volume to thereby reduce the workload on the heart.

[0017] Additional features and advantages of the invention will be set forth in the description which follows, and in part will be apparent from the description, or may be learned by practice of the invention. The objectives and other advantages of the invention will be realized and attained by the structure particularly pointed out in the written description and claims hereof as well as the appended drawings.

[0018] To achieve these and other advantages and in accordance with the purpose of the invention, as embodied and broadly described, an exemplary embodiment relates to a mechanical prosthetic heart valve including an annular housing having an inner surface, and a top surface defining at least one concave portion and at least one convex portion. The amount of the top surface defining the concave portion may be larger than the amount of the top surface defining the convex portion. At least one leaflet capture projection may extend inwardly from the inner surface of the housing, and have a substantially circular form in cross-section. At least one leaflet may be disposed adjacent to the inner surface and may be capable of rotation between an open position in which blood can flow through the heart valve and a closed position in which blood is prevented from flowing through the heart valve. The leaflet may have a main portion with leading and trailing edge surfaces, and inner and outer surfaces connecting the leading and trailing edge surfaces. The inner surface may generally define a convex curvature from the leading edge surface to the trailing edge surface, and the outer surface may generally define a convex curvature proximate the leading edge surface and a concave curvature proximate the

trailing edge surface. First and second winglet portions may be situated on opposite ends of the leaflet to facilitate rotation of the leaflet.

[0019] The top surface of the housing may define at least three concave portions and at least three convex portions. The first and second winglet portions may be situated adjacent to the inner surface of the housing in the vicinity of respective convex portions. The top surface of the housing defined by the three concave portions may be larger than the amount of the top surface defined by the convex portions, so that the inner surface area is reduced. The annular housing may be formed in a nozzle shape along the inner surface. The inner surface may include inflow projections to receive the leaflet. The valve housing may be formed from metallic material, organic material or polymeric material. The top surface of the annular housing may be scalloped shaped. The inner surface of the housing below the convex portion may be substantially solid and without perforation.

[0020] Another exemplary embodiment relates to a mechanical early-closing prosthetic heart valve including an annular housing having an inner surface, and having a top surface defining at least one concave portion and at least one convex portion. The amount of the top surface defining the concave portion may be larger than the amount of the top surface defining the convex portion. At least one leaflet capture projection may extend inwardly from the inner surface of the housing, and have a substantially circular form in cross-section. At least one leaflet may be disposed adjacent to the inner surface and be capable of rotation between an open position in which blood can flow through the heart valve and a closed position in which blood is prevented from flowing through the heart valve. The leaflet may have closure means for causing the leaflet to rotate toward a closed position prior to substantial back flow of blood through the heart valve.

[0021] The top surface of the housing may define at least three concave portions and at least three convex portions. The amount of the top surface defined by the three concave portions may be larger than the amount of the top surface defined by the three convex portions. The leaflet may have a main portion including leading and trailing edge surfaces, and inner and outer surfaces connecting the leading and trailing edge surfaces. First and second winglet portions may

be situated on opposite ends of the leaflet to facilitate rotation of the leaflet. The first and second winglet portions may be situated adjacent to the inner surface of the housing in the vicinity of respective convex portions. The top surface of the annular housing may be scalloped shaped. The inner surface of the housing below the convex portion may be substantially solid and without perforation.

[0022] Yet another exemplary embodiment relates to a mechanical prosthetic heart valve including an annular housing having an inner surface, and having a top surface defining at least three concave portions and at least three convex portions. The amount of the top surface defined by the three concave portions may be larger than the amount of the top surface defined by the three convex portions. At least one leaflet may be disposed adjacent to the inner surface and be capable of rotation between an open position in which blood can flow through the heart valve and a closed position in which blood is prevented from flowing through the heart valve. The leaflet may have a main portion including leading and trailing edge surfaces, and inner and outer surfaces connecting the leading and trailing edge surfaces. First and second winglet portions may be situated on opposite ends of the leaflet adjacent to the inner surface in the vicinity of the respective convex portions to facilitate rotation of the leaflet. First and second leaflet pivot structures may extend from the inner surface in the vicinity of the respective convex portions, and may be adapted to cooperate with the first and second winglets, respectively, to facilitate rotation of the leaflet between the open and closed positions. The first and second leaflet pivot structures each may include at least one leaflet capture projection extending inwardly from the inner surface of the housing, and have a substantially circular form in cross-section.

[0023] The heart valve may include at least three leaflets having respective first and second winglet portions, and at least three first and second leaflet pivot structures adapted to cooperate with respective first and second winglet portions. The amount of the top surface defined by the three convex portions may be a predetermined amount to facilitate rotation of the three leaflets, and the amount of the top surface defined by the three concave portions may be a predetermined amount to reduce the surface inner area of the housing. The inner surface of the housing below the convex portions may be substantially solid and without perforation.

[0024] Still another exemplary embodiment relates to a mechanical early-closing prosthetic heart valve including an annular housing having an inner surface, and having a top surface defining at least one concave portion and at least one convex portion. The amount of the top surface defining the concave portion may be larger than the amount of the top surface defining the convex portion. At least one leaflet capture projection may extend inwardly from the inner surface of the housing, and have a substantially circular form in cross-section. At least one leaflet may be disposed adjacent to the inner surface and may be capable of rotation between an open position in which blood can flow through the heart valve and a closed position in which blood is prevented from flowing through the heart valve. The leaflet may include an early-closure means for creating a tendency for the leaflet to rotate toward the closed position such that the leaflet is substantially closed prior to initiation of back flow of blood through the heart valve.

[0025] The top surface of the housing may define at least three concave portions and at least three convex portions. The amount of the top surface defined by the three concave portions may be larger than the amount of the top surface defined by the convex portions. The top surface of the annular housing may be scalloped shaped, continuous and solid. The inner surface of the housing below the convex portion may be substantially solid and without perforation.

[0026] It is to be understood that both the general description above, and the following detailed description are exemplary and explanatory and are intended to provide further explanation of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The accompanying drawings which are included to provide a further understanding of the invention and constitute a part of this specification, illustrate embodiments of the invention and together with the written description, serve to explain the principles of the invention. In the drawings:

[0028] Figure 1 is an elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position;

[0029] Figure 2A is another elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in an open position;

[0030] Figure 2B is another elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0031] Figure 2C is a side view of the multi-leaflet mechanical heart valve of Figure 2B in accordance with the present invention;

[0032] Figure 2D is another side view of the multi-leaflet mechanical heart valve of Figure 2B in accordance with the present invention;

[0033] Figure 2E is a top view of the multi-leaflet mechanical heart valve of Figure 2B in accordance with the present invention;

[0034] Figure 2F is a partial side view of the multi-leaflet mechanical heart valve of Figure 2B in accordance with the present invention;

[0035] Figure 3 is the elevated isometric view of Figure 2A in accordance with the present invention with the leaflets in the fully closed position;

[0036] Figure 4 is the elevated isometric view of Figure 2A in accordance with the present invention with the leaflets in a partially open position;

[0037] Figure 5 is a top plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position;

[0038] Figure 6 is a top plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully closed position;

[0039] Figure 7 is a bottom plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully closed position;

[0040] Figure 8 is a bottom plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position;

[0041] Figure 9 is a bottom plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0042] Figure 10 is a top plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0043] Figure 11A is an isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0044] Figure 11B is an isometric view of another preferred embodiment of a multi-leaflet mechanical heart valve, without windows;

[0045] Figure 12 is a partial cross-sectional isometric view taken along line 12'-12' in Figure 11A of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0046] Figure 13 is a cross-sectional plan view of the housing of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention;

[0047] Figure 14 is a side view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0048] Figure 15 is an isometric view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0049] Figure 16 is a front view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0050] Figure 17 is a top view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0051] Figure 18 is a bottom view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0052] Figure 19 is a top plan view of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention with three differing cross sectional views included;

[0053] Figures 19A-C are cross-sectional views of the leaflet shown in Figure 19 taken along lines 19A-19A, 19B-19B, and 19C-19C, respectively, in Figure 19;

[0054] Figure 20 is a cross-sectional view taken along line 20'-20' in Figure 17 of the profile of a preferred embodiment of a leaflet for a multi-leaflet mechanical heart valve according to the present invention;

[0055] Figure 21 is a cross-sectional view taken along line 21'-21' in Figure 5 of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position;

[0056] Figure 22 is a cross-sectional view taken along line 22'-22' in Figure 6 of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with only one of the leaflets shown in the fully closed position;

[0057] Figure 23 is partial view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed;

[0058] Figures 24A-24C are graphical representations of the performance of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention in the aortic position at three differing heart rates, respectively;

[0059] Figures 25A-25C are graphical representations of the performance of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention in the mitral position at three differing heart rates, respectively; and

[0060] Figure 26 is a cross-sectional view similar to Figure 21 which illustrates a preferred embodiment of a sewing ring for a multi-leaflet mechanical heart valve according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0061] Reference will now be made in detail to the preferred embodiments of the present invention, examples of which are illustrated in the accompanying drawings. For example, Figure 1 shows an elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position so that blood can flow through the heart valve.

[0062] As illustrated in Figure 1, the multi-leaflet mechanical heart valve **100** generally includes an annular housing **105** and rotatable leaflets **110** (as used herein, the term annular is taken to encompass any continuous surface). The housing **105** includes inner and outer circumferential surfaces, as detailed below (as used herein, the phrase circumferential surface is taken to mean the boundary surface of any closed shape). The housing **105** has three concave portions **115** and three convex portions **120** around its top surface, as well as six inflow projections **130**. Note that the inflow projections **130** extend from the inner circumferential surface of the housing **105** into the blood flow path **F**.

[0063] Housing **105** may be constructed of any rigid biocompatible material. For example, housing **105** may be constructed from any biocompatible metallic material, such as chromium, nickel-tungsten, and titanium. Housing **105** may also be constructed of any rigid biocompatible organic material such as, for example, pyrolytic carbon. Furthermore, housing **105** may be constructed from any biocompatible polymeric material, such as a biocompatible plastic material. In the preferred embodiment, housing **105** is machined from a solid metallic rod.

[0064] Like housing **105**, the leaflets **110** may be constructed of any rigid biocompatible material (metallic, organic, or polymeric). In the preferred embodiment, leaflets **110** are preferably fabricated from pyrolytic carbon. The leaflets **110** of the preferred embodiment have two complex curved, non-parallel surfaces.

[0065] Figure 2A shows an elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets **110** rotated to an open position. Figure 2A also more clearly illustrates the structure on housing **105** which facilitates rotation of and retains leaflets **110**. Housing 105 can include six openings therein (called windows herein) **125**. Each leaflet **110** has two winglets **205** (angled portions at the ends of each of the leaflets) with a main portion disposed therebetween. Winglets **205** rest on inflow projections **130** (at least when the leaflets are in the closed position). In addition to the six inflow projections **130**, housing **105** also has three closing projections **200**, six winglet guide paths **210**, and six winglet guide arcs **215**. The leaflet pivot structure of the heart valve of the preferred embodiment which retains the leaflets **110** and its winglets **205** within the housing **105**

may be informatively compared to the structure described in U.S. Patent No. 5,123,918 which is incorporated by reference herein. As shown in Figure 2A, windows **125** communicate with the blood flow through the heart valve **100** at regions denoted as **220**. Thus, windows **125** allow blood to flow across the back of the winglets **205** and substantially wash the leaflet pivot region in both the open and closed positions. This washing helps to greatly reduce blood stagnation behind the winglets **205**, and thus reduces the likelihood of formation of a local blood clot or thrombus in this region.

[0066] Note that the windows **125** may be made any shape and size which allows for appropriate structural rigidity in the housing **105** and optimum washing flow through the windows and into the leaflet pivot region. In the preferred embodiment, windows **125** are triangular in shape. Of course, windows **125** may be omitted altogether.

[0067] Although housing **105** may be made in any annular shape, the housing of the preferred embodiment has three concave portions **115** and three convex portions **120** around the top surface of its circumference, *i.e.*, a scalloped arrangement. These concave portions **115** and convex portions **120** play a special role during the surgical implantation of valve prosthesis **100**. During implantation, a sewing ring (see Figure 26, for example) is attached to the outer circumference of housing **105**. The surgeon then stitches through the tissue and through the sewing ring to attach the valve in its desired location. If the surgeon inadvertently places one or more of the stitches around the housing **105**, when the stitches are pulled tight, the geometry of housing **105** will move the misplaced stitches towards concave portions **115** rather than convex portions **120**. Thus, there is little opportunity for a suture to be looped over the convex portions **120** of the housing **105** and thereby impede the opening and closing of the leaflets **110**.

[0068] With regard to Figs. 2B-2D, the concave portions **115** and convex portions **120** of the housing **105** can be formed in a scalloped shape. A top surface of the housing is preferably solid and continuous. The scalloped arrangement of concave portions **115** and convex portions **120** reduces the wetted surface area of the inner surface of housing **105**. Reduction of the wetted surface area facilitates optimum fluid flow performance, reduces head loss and helps prevent thrombosis and thrombo-embolisms. Figures 2B and 2C illustrate a scalloped arrangement of

housing **105** having a reduced wetted surface area, such that concave portions **115** comprise a large portion of the top surface of the circumference of housing **105**. However, the portion of the top surface of the circumference of housing **105** that is comprised of concave portions **115** has a practical limit. For a fixed circumference of housing **105**, as concave portions **115** comprise a larger portion of the circumference, convex portions **120** comprise a smaller portion of the circumference. If the portion of the circumference comprised of convex portions **120** becomes too small, the inner circumferential surface of housing **105** in the vicinity of convex portions **120** becomes too small, such that the operation of the valve hinge mechanism is adversely affected.

[0069] As shown in Fig. 2F, the area of the convex portion **120** from a side view is preferably within a certain range. Specifically, it is preferred that the area of the convex portion is large enough to maintain support for the hinge pivot structures, including the leaflet capture projections **300**. The leaflet capture projections **300** are preferably substantially spherical in shape. However, it is possible that the leaflet capture projections **300** are less than spherical, and approximately hemispherical in shape due to the size reduction of the convex portions **120**. The depth and width of the concave/convex/scalloped shaped portions of the side wall of the annular housing determines the amount and shape of the leaflet capture projections **300** that can remain. As shown in Fig. 2F, concave portion **115** can be scalloped shaped such that it narrowly avoids substantial re-shaping of the typically spherical or semispherical leaflet capture projections 300. Thus, the least amount of surface area is provided while maintaining the functional structures of the housing.

[0070] Figure 3 is an elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully closed position to prevent blood flow through the heart valve. Housing **105** can also include six leaflet capture projections **300** which help to prevent the leaflets **110** from being easily removed from their pivot/hinge structures. The effective closing angle of the complex curved leaflet may be defined by the chord of the leaflet in its middle section. Note that in the preferred embodiment, the chord of leaflets **110** preferably close to an angle of about 30° to about 40° with respect to the inflow plane of the housing **105**.

[0071] With the leaflets **110** in the closed position, the angle or pyramid shape of the closed leaflets **110** also channels the flow through the windows **125** of the valve housing **105** which results in improved washing by blood flow across the back of the winglets **205** and completely washes the leaflet pivot region. Again, this washing helps to greatly reduce blood stagnation behind the winglets **205**, and thus reduces the likelihood of formation of a local blood clot or thrombus in this region.

[0072] Figure 4 shows an elevated isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets rotated into a partially open position (50% open - half way between the fully open position and the fully closed position). In this position as well as any position in which the leaflets **110** are at least partially open, blood flows across the back surface of the leaflets **110** and through the windows **125** to completely wash the leaflet pivot region. As mentioned above, this washing helps to greatly reduce blood stagnation behind the winglets **205**, and thus reduces the likelihood of formation of a local blood clot or thrombus in this region.

[0073] Figure 5 is a top plan view and Figure 8 is a bottom plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully open position. As shown, the open leaflets **110** divide the blood flow through the valve **100** into several distinct flow paths. Main flow path **500** extends along the central axis of valve **100**, while outer flow paths **505** are delineated by the open leaflets **110**. Note, as shown in Figs. 1 and 2A, winglets **205** of leaflets **110** do not completely cover windows **125** when leaflets **110** are in the open position. Thus, in this position, as well as any open position, blood flows through windows **125** to completely wash the leaflet pivot region, reducing the possibility of stagnation or blood coagulation in this region.

[0074] Although the opening angle of the leaflets **110** may be optimized for differing requirements, the chord of the leaflets **110** of the preferred embodiment open to an effective angle of about 75° to about 90° with respect to the inflow plane of the housing **105**. The effective opening angle of the complex curved leaflet may be defined by the chord of the leaflet in its middle section. This opening angle, coupled with the unique contour of the leaflets,

provides for a central flow valve, similar to the natural valves of the heart. This results in a reduced pressure gradient or pressure drop across the valve in the open position when compared with most conventional mechanical heart valves.

[0075] Figure 6 is a top plan view and Figure 7 is a bottom plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets in the fully closed position. As shown, in the preferred embodiment, the leaflets **110** close the main and outer flow paths **500** and **505** respectively. However, in some instances, it may be desirable to leave a small gap between the leaflets in the closed position. It has been discovered that a small gap, while allowing for minor static leakage, tends to improve some performance characteristics, *e.g.*, reduces the harmful effects of cavitation (by increasing the cavitation threshold) at the trailing surfaces of the leaflets during closing. This small gap need not be continuous or constant along the intersection of the leaflets **110**. It may be a gap which is widest at the pointed tips of the leaflets **110** and get progressively narrower radially towards the housing **105**. It is noted that a very small opening between the leaflets only near their tips is shown in the figures (due to manufacturing).

[0076] Figure 9 is a bottom plan view and Figure 10 is a top plan view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets **110** removed. This figure illustrates the structure on housing **105** which facilitates rotation of and retains leaflets **110**. As shown, this structure includes six inflow projections **130**, three closing projections **200**, six winglet guide paths **210**, six leaflet capture projections **300**, and six winglet guide arcs **215**.

[0077] Figure 11A is an isometric view of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed. As shown, each window **125** is placed just above a winglet guide path **210**, the winglet guide path **210** being defined between an inflow projection **130** and a closing projection **200**. Also shown in this figure is the sewing ring receiving portion **1100** of housing **105**. Although in the preferred embodiment sewing ring receiving portion **1100** is an extended part of housing **105**, other sewing ring attachment arrangements could be considered. Figure 11B is an isometric view of

another preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed, and without windows **125**.

[0078] Figure 12 is a partial cross-sectional isometric view taken along line 12'-12' in Figure 11A of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets removed. As illustrated, inflow projection **130** includes a non-uniform surface portion **1205**. It has been discovered through testing that additional wear resistance may be achieved through the use of this non-uniform, asymmetrical surface on one side of the inflow projection **130** as it mates with a complementary seating surface on each leaflet **110** (provides for surface interface contact rather than point interface contact).

[0079] Figure 13 is a cross-sectional plan view of the housing **105** of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention. Although differing cross-sections could be considered, in the preferred embodiment, a converging nozzle cross-section is utilized. As shown, housing **105** of the preferred embodiment includes converging section **1200** as well as sewing ring receiving portion **1100**. Thus, housing **105** of the preferred embodiment converges in the flow direction **F** which minimizes flow separation and turbulence on the inflow side of the valve during forward flow through the open valve. The converging nozzle also reduces the pressure drop or pressure gradient across the valve during forward flow through the open valve when compared to other heart valves which have a rather abrupt or blunt shape on the inflow side of the housing. Thus, the housing of the preferred embodiment has improved flow characteristics and minimizes pressure or energy losses and flow separation through the open valve.

[0080] Figure 14 is a side view of a preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention. The preferred embodiment of the leaflet **110** according to the present invention includes a winglet **205** at each side of the main portion of the leaflet **110**. Figure 15 is an isometric view of a preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention. The main portion comprises inner flow surface **1400**, outer flow surface **1405**, leading edge surface **1410**, and trailing edge surface **1415**. As mentioned above, leaflet **110** includes two winglet seating

portions **1500** which mate with inflow projections **130**. As depicted in this figure, outer flow surface **1405** of leaflet **110** is concave along a line extending between the winglets **205**.

[0081] Although the preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention is somewhat triangular in shape (because three leaflets are utilized), other shapes and numbers of leaflets may be utilized without departing from the scope or spirit of the present invention.

[0082] Figure 16 is a front view, Figure 17 is a top view, and Figure 18 is a bottom view of a preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention. As shown in these figures, winglets **205** include winglet outer surface **1600** and winglet inner surface **1605**. Winglet outer surface **1600** is the surface that is washed by the blood flow through windows **125**. As depicted in Figure 18, inner flow surface **1400** of leaflet **110** is convex along a line extending between winglets **205**.

[0083] Figure 19 is a top plan view of a preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention with three differing cross sectional views included. The section cuts (A, B, and C) show the changing cross section of the preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention from centerline A-A to just short of winglet **205**. As can be seen, section A-A shows a cut of varying thicknesses and contours, and section C-C near the winglet **205** shows a cut with a lesser variation in thickness and less pronounced contours. Section B-B shows an intermediate cut exemplifying the transition between A-A and C-C. Preferably, the leaflet is symmetric about section A-A.

[0084] Figure 20 is a cross-sectional view taken along line 20'-20' in Figure 17 of the profile of a preferred embodiment of a leaflet **110** for a multi-leaflet mechanical heart valve according to the present invention. As shown, inner flow surface **1400** has a convex curvature from leading edge surface **1410** to trailing edge surface **1415**. Outer flow surface **1405** has an S-shaped curvature from leading edge surface **1410** to trailing edge surface **1415**. Outer flow surface **1405** has a convex curvature **2005** proximate the leading edge surface **1410**. Furthermore, outer flow surface **1405** has a concave curvature **2010** proximate the trailing edge surface **1415**.

[0085] The shape of the preferred embodiment of the leaflets **110** minimizes flow separation in the open position and enhances early closure of the leaflets. As will be appreciated by one skilled in the art of fluid mechanics, the shape of the leaflet **110** affects the pressure distribution over its surface as the blood flows over the around it. As shown in Figure 20, leaflet **110** according to the present invention has an approximate virtual pivot axis at a location shown at **2000**. Thus, during operation the pressure distribution over the leaflet will affect the rotational tendency of leaflet about the virtual pivot axis **2000**.

[0086] Given the shape of the inner and outer flow surfaces, the differences between the static surface pressure along the inner flow surface $\mathbf{P_I}$ and the outer flow surface $\mathbf{P_O}$ and in view of the location of virtual pivot axis at a location shown approximately at **2000**, the leaflet **110** is caused to tend towards rotation to a closed position. These pressure differentials are created by the airfoil-like shape of the leaflet **110** in the flow direction **F**. The fluid mechanics (including pressure gradients thereof during flow) of an airfoil are well known to those skilled in the fluid mechanics art. The early closure of the mechanical heart valve according to a preferred embodiment of the present invention starts as flow **F** through the valve **100** decelerates and the pressure field reverses. In the aortic position the leaflets **110** are substantially closed before the flow reverses, similar to the function of a natural aortic valve.

[0087] In another aspect, the inner and outer flow surfaces, **1400** and **1405**, respectively, are advantageously designed such that in fully opened position of the leaflets the surface tangents of both flow surfaces at the trailing edge surface **1415** and the outer flow surface **1405** at the leading edge surface **1410** are substantially aligned in the direction of flow **F** to limit flow separation and eddy formation (turbulence) as blood flow leaves the trailing edge surface **1415** of the open leaflets **110**. In accordance with a preferred embodiment of the present invention, the surface tangent of the inner flow surface **1400** proximate the leading edge surface **1410** of the leaflet **110** forms an angle of preferably about 0° to about 30° with respect to the flow direction. Thus, flow separation on both the inner and outer surfaces, **1400** and **1405**, respectively, of the leaflet **110** is minimized. Accordingly the leaflets **110** of the mechanical heart valve **100**

according to the present invention reduce turbulence, flow separation, and energy losses associated with flow through the open valve.

[0088] Figure 21 is a cross-sectional view taken along line 21'-21' in Figure 5 of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets **110** in the fully open position. Figure 21 clearly illustrates the interaction of winglets **205** with the winglet guide paths **210** and winglet guide arcs **215**. Also, this figure shows that the distance between inflow projections **130** and the closing projection **200** decreases in the blood flow direction. Thus, winglet guide paths **210** create a nozzle effect to direct blood flow through windows **125** to substantially wash the rear surface of winglets **205** to minimize stagnation.

[0089] Figure 22 is a cross-sectional view taken along line 22'-22' in Figure 6 of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with only one of the leaflets **110** shown in the fully closed position. As shown, when in the closed position, leaflet **110** rests upon inflow projections **130** and the closing projection **200**. As also illustrated in this figure, leaflet capture projections **300** help to retain leaflet **110** in housing **105**.

[0090] Figure 23 is an enlarged cross-sectional view taken along line 21'-21' in Figure 5 of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention with the leaflets **110** removed. Like Figure 21, this figure shows that the distance between inflow projections **130** and the closing projection **200** decreases in the blood flow direction due to the widening shape of the projections **130, 200**. Thus, winglet guide paths **210** act as nozzles to direct blood flow through windows **125**. This nozzle creates increased flow velocity into and around the windows **125** and winglet guide arcs **215**. This figure also shows the aerodynamic and smoothed sculpting of inflow projections **130** and the closing projection **200** in the blood flow direction. These aerodynamic profiles help to limit flow separation and eddy formation (turbulence) as blood flows across these elements.

[0091] Figures 24A-24C and 25A-25C are graphical representations of the performance of a preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention in the aortic and mitral positions respectively at three differing heart rates (50, 70, and

120 beats per minute). As shown figures 24A-24C in the aortic position, the preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention begins to close very early. In fact, as illustrated, closure begins just after the flow peak (as flow decelerates and the pressure field reverses) and the valve the leaflets are substantially closed before the flow reverses (at V=0), similar to the function of a natural aortic valve. This early closure time is made possible by the flow characteristics of the preferred valve housing **105** as well as the preferred leaflets **110** which tend towards closure because of their novel geometry.

[0092] This closing behavior differs dramatically from that of conventional mechanical valve prostheses. As mentioned above, in conventional mechanical valve prostheses at the time when the flow rate becomes zero through the valve, conventional mechanical valve prostheses remain 90% open. Thus, with conventional mechanical valve prostheses, a significant portion of the closure (more than 90%) occurs during regurgitation (backward flow) of blood through the valve, and thus the closure is very rapid and entails a large amount of dynamic leakage (regurgitation). Thus, this very rapid closing under high pressure backward flow can lead to numerous undesirable results (cavitation, HITS, and unnecessary stress on the heart muscle). In contrast, the preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention begins to close just after the flow peak (as flow decelerates and the pressure field reverses) and the valve's leaflets are substantially closed (approximately 90%) before the flow reverses (at V=0). Thus, the preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention begins to close early and begins to close very slowly. Because the leaflets are almost completely closed prior to the initiation of the high pressure backward flow, the preferred embodiment of a multi-leaflet mechanical heart valve according to the present invention reduces the likelihood of cavitation, HITS, blood trauma, and regurgitation.

[0093] Of course, it should be understood that the closure performance of the present invention could be adjusted to meet desired criteria, such as a desired closing percentage at zero flow velocity (initiation of backwards flow), or timing of the initiation of closure rotation with respect to the maximum flow velocity. Preferable adjustments to the design could comprise modification of the airfoil-like geometry of the leaflets **110** to affect the pressure distributions

along the inner and outer flow surfaces **1400** and **1405**, respectively, a structural modification to the pivot structure to relocate the virtual pivot point of the leaflet, a reshaping of the leaflet to alter its center of mass or its neutral point, etc. The present invention conceives that optimal valve closure performance occurs between 50% to > 90% closed before the flow reverses.

[0094] Finally, Figure 26 is a cross-sectional view similar to Figure 21 which illustrates a preferred embodiment of a sewing ring for a multi-leaflet mechanical heart valve (in the aortic position) according to the present invention. As shown, this preferred sewing ring is attached to the outer circumference of housing **105** at sewing ring receiving portion **1100**.

[0095] As illustrated in the detailed description, the improved mechanical heart valve for implantation into a patient in accordance with the present invention substantially eliminates one or more of the problems or disadvantages found in the prior art. The novel structure, as particularly pointed out in the written description and the appended drawings hereof, provides a improved mechanical heart valve for implantation into a patient which provides improved flow characteristics, minimizes blood clotting behind the leaflets, and provides more natural opening and closing behavior.

[0096] It will be apparent to those skilled in the art that various modifications and variations can be made in the mechanical heart valve for implantation into a patient of the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the disclosure hereof and any equivalents of the structures disclosed herein.